



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/670,378

09/26/2003

Thomas DeWitt Smith

11051-0002

6905

22902

7590

11/18/2009

CLARK & BRODY

1090 VERMONT AVENUE, NW

SUITE 250

WASHINGTON, DC 20005

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

11/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS DEWITT SMITH,
Appellant

Appeal 2009-014042
Application 10/670,378
Technology Center 1600

Decided: November 18, 2009

Before CAROL A. SPIEGEL, RICHARD M. LEBOVITZ, and
STEPHEN WALSH, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant appeals under 35 U.S.C. § 134(a) from an Examiner's final rejection of all pending claims, i.e., claims 6, 7, 9, 17, 18, 20, 21, 26, 37, and 41. We have jurisdiction under 35 U.S.C. § 134. We AFFIRM-IN-PART.

I. Statement of the Case

The subject matter on appeal is directed to methods of making an emulsified absorption base. According to the 378 application (herein after "Spec."), "[a]n absorption base is petrolatum with the addition of an emulsifier such that, upon addition of water, it will combine with water of an equal weight to form a homogeneous and acceptable pharmaceutical end product" (Spec. 2:16-19). The invention recited in claim 17 is to a method of making the base with all non-lanolin based emulsifiers having a HLB (i.e., a hydrophilic-lipophilic balance) value of 1-7, preferably an glucose-derived emulsifier such as methyl glucose dioleate (*id.* 4:11-15; claim 6).

Claims 17 and 6 are illustrative and read as follows¹ (Claims Appendix, Br. 19-20):

17. A method of making an emulsified absorption base comprising:

- a) heating white petrolatum up to 80°C; and
- b) adding an effective amount of a non-lanolin based emulsifier that falls within the range of 3 HLB units of the HLB value of petrolatum (HLB 4) to the white petrolatum and mixing the two components together to form the absorption base; and diluting the absorption base with water preheated to up to 50°C to form an emulsified absorption base for skin use alone or skin use when the emulsified absorption base is combined with other ingredients.

6. A method of making an emulsified absorption base comprising:

¹ Appeal Brief filed 4 February 2009 (hereinafter "Br.").

- a) heating white petrolatum up to 80°C; and
- b) adding an effective amount of methyl glucose dioleate to the white petrolatum and mixing the two components together to form an absorption base; and
- c) diluting the absorption base with water preheated to up to 50°C to form the emulsified absorption base for skin use alone or skin use when the emulsified absorption base is combined with other ingredients.

The Examiner has rejected claims 6, 7, 9, 17, 18, 20, 21, 26, 37, and 41 as unpatentable under 35 U.S.C. § 103(a) over Narula² and McAtee³ (Ans.⁴ 3-4).

According to the Examiner, Narula teaches making oil-in-water emulsions comprising petrolatum diluted with water but does not teach heating the petrolatum up to 80°C or diluting the emulsion with water preheated up to 50°C (Ans. 3). The Examiner found that McAtee teaches a conditioning emulsion comprising an oil soluble conditioning agent, such as petrolatum, and a methyl glucose dioleate emulsifier (Ans. 3). The Examiner also found that Examples 6-10 of McAtee disclose mixing the ingredients of the conditioning emulsion at between 75-110°C (Ans. 3-4). Thus, the Examiner concluded that it would have been obvious to combine the petrolatum and methyl glucose dioleate emulsifiers of Narula and McAtee for maximal conditioning benefits (Ans. 4 and 6). The Examiner further concluded that it would have been obvious to optimize the

² U.S. Patent 4,788,001, *Oil-In-Water Emulsion*, issued 29 November 1988 to Dipak Narula (hereinafter "Narula").

³ U.S. Patent 6,153,208, *Cleansing and Conditioning Article for Skin or Hair*, issued 28 November 2000 to McAtee et al. (hereinafter "McAtee").

⁴ Examiner's Answer mailed 28 April 2009 (hereinafter "Ans.").

temperature used to form the emulsion to provide a stable, uniform composition (Ans. 4 and 6).

Appellant argues that Narula and McAtee are not properly combinable because the former describes an oil-in-water emulsion which requires water in a specific amount while the latter describes a water-free composition comprising a water-in-oil emulsion (Br. 9-11 and 14-15). Appellant points out that McAtee uses high mixing temperatures because of the high melting points of the lipid hardeners used in the conditioning component and, therefore, since Narula does not use high melting point lipid hardeners, there is no reason to modify Narula based on McAtee (Br. 11-13). Furthermore, according to Appellant, it is unclear how McAtee would have motivated one of ordinary skill in the art to preheat the water used to dilute the claimed mixture (Br. 14). Appellant also points out that, contrary to the Examiner's assertion, "both" petrolatum and methyl glucose dioleate are not emulsifiers. Rather, methyl glucose dioleate is an emulsifier that, when combined with petrolatum, produces an emulsified mixture, i.e., the claimed absorption base (Br. 15-16). Finally, Appellant argues that the Examiner has articulated no reason for picking the methyl glucose dioleate emulsifier of McAtee from the many emulsifiers disclosed as useful in the conditioning component and adding it to petrolatum heated to up to 80°C, and then diluting the mixture with preheated water as required by claim 6 (Br. 16).

Appellant separately argues the patentability of claims 6 and 17 (Br. 9). Therefore, we decide this appeal on the basis of claims 6 and 17. 37 C.F.R. § 41.37(c)(1)(vii). At issue is whether Appellant has shown (A) that Narula and McAtee are not properly combinable, (B) that the Examiner erred in failing to articulate a reason for heating the petrolatum up to 80°C or

diluting the emulsion with water preheated up to 50°C based on the teachings of Narula and McAtee, and (C) that the Examiner used hindsight reconstruction to select the dimethyl glucose dioleate emulsifier of McAtee to form the oil-in-water emulsion of Narula.

II. Legal Principles

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). "Often, it will be necessary . . . to look to interrelated teachings of multiple [references] . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). "[T]his analysis should be made explicit", *id.* at 418, and it "can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* "The combination of familiar elements according to known methods is likely to be obvious when it does not more than yield predictable results." *Id.* at 416.

In addition, one skilled in the art must be presumed to know something about the art apart from what the references disclose. *In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962). Skill in the art is presumed. *In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985). It is well settled that the prior art need not disclose the same purpose for a claimed method in order to

establish its obviousness under 35 U.S.C. § 103. *In re Dillon*, 919 F.2d 688, 693 (Fed. Cir. 1990). All that is necessary is that one of ordinary skill in the art would have had some reason for performing the claimed method step. *In re Kemps*, 97 F.3d 1427, 1430 (Fed. Cir. 1996). However, “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

Further, although § 103 does not define what is meant by "prior art,"

this determination is frequently couched in terms of whether the art is analogous or not, i.e., whether the art is "too remote to be treated as prior art." *In re Sovish*, 769 F.2d 738, 741 . . . (Fed. Cir. 1985).

.

Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979).

In re Clay, 966 F.2d 656, 658-59 (Fed. Cir. 1992).

III. Findings of Fact

The following findings of fact (hereinafter "FF") are supported by a preponderance of the evidence of record.

A. Narula

[1] Narula discloses processes and compositions which incorporate nonionic primary, secondary, and tertiary surfactants (emulsifiers) to

- aid in the formation and stabilization of oil-in-water emulsions (Narula 6:1-4).
- [2] Suitable water-insoluble oils for emulsifying include petrolatum (Narula 3:6-19).
- [3] The primary, secondary, and tertiary surfactants may be of the same or different type, provided they are nonionic (Narula 6:13-15).
- [4] The primary surfactant has an HBL value of 13 to 15 and, preferably, is an ethoxylated alkylphenol, such as octoxynol-13 (Narula 6:16-22).
- [5] The secondary surfactant has an HBL value of 7 to 9 and, preferably, is an ethoxylated alkylphenol, such as octoxynol-3 (Narula 6:35-41).
- [6] The tertiary surfactant has an HBL value of at least 16 and, preferably, is an ethoxylated saccharide, such as polyethoxylated methyl glucose diolate containing about 120 ethylene oxide units per molecule, i.e., PEG-120 methyl glucose dioleate (Narula 6:42-48).
- [7] Preferably, the emulsions are made by mixing an aqueous phase containing water and the nonionic tertiary surfactant with an oil phase containing the water-insoluble oil and the nonionic primary and secondary surfactants, although the aqueous and oil phases may be mixed in any manner (Narula 7:64-8:5).
- [8] In one embodiment, Narula suggests heating both the aqueous and oil phases prior to intermixing them in an attempt to get a better emulsion (Narula 9:10-13).
- B. McAtee
- [9] McAtee discloses a disposable, single use cleansing and conditioning washcloth-like article containing a conditioning component (McAtee 3:58-61; 4:38-51).

- [10] The conditioning component may comprise a water soluble conditioning agent, an oil soluble conditioning agent, a conditioning emulsion, or combination or permutation thereof (McAtee 24:41-44).
- [11] The conditioning emulsion is a water-in-oil emulsion, i.e., a combination of an internal phase comprising a water soluble conditioning agent that is enveloped by an external phase comprising an oil soluble agent (McAtee 28:66-29:2).
- [12] The emulsifier(s) used to form the conditioning emulsion has a low HLB value, typically in the range of about 1 to about 7 (McAtee 30:12-17).
- [13] Suitable emulsifiers include methyl glucose esters of C₁₆-C₂₂ fatty acids, such as methyl glucose dioleate (McAtee 30:42-67).
- [14] The conditioning component may further include lipid hardening materials, such as petrolatum (McAtee 7:54-56 and 32:19-25).
- [15] Examples 6-10 describe forming a conditioning emulsion by mixing an oil phase including petrolatum and polyglyceryl tristearate at between 75-115°C until molten, stopping heating, slowly adding a homogeneous aqueous phase while continuing to mix, and then cooling to room temperature (McAtee 54:48-55:11).

IV. Analysis

A. Narula and McAtee are properly combinable

Narula and McAtee are both directed to the same field of endeavor, i.e., the field of emulsions. It is well known that emulsions consist of one liquid suspended in another. Both Narula and McAtee discuss emulsifiers and their properties, such as their HLB values, as well as their usefulness in preparing emulsions. Therefore, since Narula and McAtee fulfill the first

criterion for determining whether prior art is analogous under *Deminski*, *Wood*, and *Clay*, Appellant's argument that they are not properly combinable is without merit.

- B. The prior art fairly teaches or suggests heating both aqueous and oil phases used to make the emulsion prior to their intermixing

The method of claim 17 comprises heating petrolatum up to 80°C, adding a non-lanolin based emulsifier having an HLB value of 1-7, and diluting with water preheated up to 50°C to form an emulsified absorption base (Br. 20). The prior art need not disclose the same purpose for a claimed method in order to establish its obviousness under 35 U.S.C. § 103. *Dillon*, 919 F.2d at 693. All that is necessary is that one of ordinary skill in the art would have had some reason for performing the claimed method step. *Kemps*, 97 F.3d at 1430. Here, Narula teaches mixing an aqueous phase with an oil phase containing petrolatum and a nonionic secondary surfactant, preferably an ethoxylated alkyl phenol having a HLB value of 7-9 (FF 1, 2, 5, and 7). The Examiner expressly concluded that it would have been obvious to optimize the temperatures to provide a stable, uniform emulsion (Ans. 4 and 6), thereby arriving at temperatures recited in the claimed method steps. Indeed, the Examiner's position comports with logic and basic scientific knowledge.

To wit, since an emulsion consists of one liquid suspended in another, it is only logical for the petrolatum in the oil phase to be in liquid form, i.e., to melt the petrolatum. Regardless of the use to which the petrolatum is being put, whether as a water-insoluble oil per Narula or as a hardening agent per McAtee, the melting point of petrolatum is an inherent property of the compound, not its use (see e.g., Ans. 6). Therefore, it would have been

obvious to heat the petrolatum up to 80°C as taught by McAtee (FF 15) to obtain a molten, i.e., liquid petrolatum, in order to form an emulsion. To hold otherwise, is to hold that one of ordinary skill in the art is without skill. *Sovish*, 769 F.2d at 743.

Similarly, it would also have been logical and obvious to heat the aqueous phase being mixed with the heated oil phase when using an ethoxylated surfactant as the emulsifier (after which the mixture is allowed to cool) as taught by Narula. Again, we understand the Examiner's position to be based on general knowledge in the art, knowledge which is consistent with the teachings of Narula and McAtee that temperature is a recognized parameter to vary when making emulsions to enhance mixing and stability (Ans. 4; FF 8, 15). Therefore, we agree with the Examiner that it would have been a matter of routine optimization to heat both the aqueous and oil phases prior to their intermixing as claimed to obtain a better emulsion consistent with the teachings and ingredients of Narula and McAtee and the general knowledge of one of ordinary skill in the art. We note Appellant has not provided evidence rebutting the Examiner's *prima facie* conclusion of obviousness. Thus, we sustain the rejection of claim 17 and its dependent claims under § 103 over Narula and McAtee. However, claim 6 stands on a different footing than claim 17.

- C. The Examiner has failed to provide a legally sufficient reason for selecting the dimethyl glucose dioleate emulsifier of McAtee for use in forming the oil-in-water emulsion of Narula

The method of claim 6, unlike the method of claim 17, requires a specific emulsifier, dimethyl glucose dioleate. The Examiner has not pointed to, and we do not find, where Narula teaches or suggests dimethyl glucose dioleate to be a suitable surfactant (emulsifier) for its claimed

method. Narula consistently describes the use of surfactants with specific HBL values and discloses preferred ethoxylated surfactants (FF 4-6). The Examiner has not established, for example, what the HLB value of dimethyl glucose dioleate is or found it to be an ethoxylated surfactant or identified any other factual basis for selecting it to form an oil-in-water emulsion. Instead, the Examiner relied on McAtee "to teach that conditioning emulsions can be formulated with the same components of the instant invention" (Ans. 6). Therefore, we agree with Appellant that the Examiner did not provide a sufficient factual basis to support her *prima facie* conclusion as to claim 6, but rather used hindsight reconstruction to pick and choose dimethyl glucose dioleate from the myriad emulsifiers disclosed by McAtee and to use it to form the oil-in-water emulsion of Narula. Therefore, we reverse the rejection of claim 6 and its dependent claims under § 103 over Narula and McAtee.

D. Conclusion

We reverse the rejection of claim 6 and dependent claims 7, 9, 21, and 26, but sustain the rejection of claims 17, 18, 20, 37, and 41, under 35 U.S.C. § 103 over Narula and McAtee. Appellant has not shown that Narula and McAtee are not properly combinable or that the Examiner erred in failing to articulate a reason for heating the petrolatum up to 80°C or diluting the emulsion with water preheated up to 50°C based on the teachings of Narula and McAtee. However, Appellant has shown that the Examiner used hindsight reconstruction to select the dimethyl glucose dioleate emulsifier of McAtee to form the oil-in-water emulsion of Narula.

V. Order

Upon consideration of the record, and for the reasons given, it is
ORDERED that the decision of the Examiner to reject claims 6, 7, 9,
21, and 26 as unpatentable under 35 U.S.C. § 103(a) over Narula and
McAtee is REVERSED;

FURTHER ORDERED that the decision of the Examiner to reject
claims 17, 18, 20, 37, and 41 as unpatentable under 35 U.S.C. § 103(a) over
Narula and McAtee is AFFIRMED; and,

FURTHER ORDERED that no time period for taking any subsequent
action in connection with this appeal may be extended under 37 C.F.R.
§ 1.136(a)(1)(a)(iv).

AFFIRMED-IN-PART

rvb

CLARK & BRODY
1090 Vermont Avenue, NW, Suite 250
Washington, DC 20005